EPA Registration No. 66171-7 Vol. 3

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 66171-7
Send to SIG: check box [X]

This material is:

New stamped label accepted label
New CSF
Notification
Final Printed Label
€ Other:
€

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Jacqueline McFarlane

Phone: 703 308-6416 Division: AD

Date: 10/16/2006

Current as of July 12, 2006

AUG 2 2 2006

Mr. Gary Gunner
Preserve International
P.O. Box 17003
Reno, NV 89511

Subject: Synergize
EPA Registration No.: 66171-7
Amendment Date: February 16, 2006
EPA Receipt Date: February 27, 2006

Dear Mr. Gunner,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with conditions listed below.

- Add Additional Organisms, Avian Influenza A (H3N2) virus (Avian Reassortant) and Escherichia coli (F-18)

Conditions
Revise the label as follows:

1) The species name of *Salmonella choleraeusis* (ATCC 10708) has been changed by ATCC to *Salmonella **enterica***. Your label will need to reflect this organism name change. Also, you must list the ATCC virucidal designation for Avian Influenza by stating Avian Influenza A (H3N2) virus (Avian Reassortant).

2) Fiberglass is a porous surface. You must qualify fiberglass as a hard nonporous surface by listing specific surfaces made of sealed fiberglass such as sinks and tubs."

3) After #7 under the "Directions for use in Poultry House," add the heading, "Directions for Hatchery Room Fogging." Revise the directions to reflect the following:

Remove all animals, feed, food products and packaging from premises. Remove all litter and manure from floors, walls, and surfaces of room to be treated. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix 0.25 to 1 oz per gallon of water then fog using one quart per 1000 cubic feet of room area. When fogging is complete ventilate building and other closed spaces. All areas of personnel, poultry, and feeds must be vacated for a minimum of 2 hours after fogging. Thoroughly clean all food contact surfaces including feeding and watering appliances with soap or detergent and rinsed with potable water before

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Efficacy of Disinfectants – Avian Influenza A (H3N2) virus (Avian Reassortant)	Submitted study, MRID 467703-01	Acceptable, 1:256 dilution in 5% serum for 10 minutes in 1000 ppm hard water
AOAC Use Dilution Method - E. coli (F-18)	Submitted study, MRID 467703-02	Acceptable, 1:256 dilution in 5% serum for 10 minutes in 1000 ppm hard water

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
Efficacy Data Evaluation

CONCURRENCES								
SYMBOL								
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Acceptable Data

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Virucidal Efficacy of Disinfectants – Avian Influenza A (H3N2) virus (Avian Reassortant)	Submitted study, MRID 467703-01	Acceptable, 1:256 dilution in 5% serum for 10 minutes in 1000 ppm hard water
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Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
Efficacy Data Evaluation

SYNERGIZE®

CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C. 6538 — Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella choleraesuis A.T.C.C. 10708 — Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS) — Avian Influenza
Escherichia Coli F18

ACTIVE INGREDIENTS

Alkyl (C_{12} 67%, C_{14} 25%, C_{16} 7%, C_{18} 1%) dimethyl benzyl ammonium chloride	26.00%
Glutaraldehyde	7.00%
INERT INGREDIENTS	67.00%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

PESTICIDE STORAGE:
Store away from heat. Do not transfer to another container. Do not reuse empty container

CONTAINER DISPOSAL:
Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PESTICIDE DISPOSAL:
Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

EPA Registration No.: 66171-7
EPA Establishment No.: 66171-CA-001
66171-CA-002
Patent Number: 5,891,922

NFPA HAZARD CLASSIFICATION

HEALTH	FIRE	REACTIVITY	SPECIFIC
3	1	1	None

DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm $CaCO_3$) and performs especially well in areas containing 5% serum.
SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.
SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.
VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or course spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

1) Remove all animals and feed from the premises, vehicles and enclosures.
2) Empty all troughs, racks, and other feeding and watering appliances.
3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

1) Do not use in milking stalls, milking parlors, or milk houses.
2) Remove all animals and feed from the premises, vehicles, and enclosures.
3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
4) Empty all troughs, racks, and other feeding and watering appliances.
5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.
7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR USE IN POULTRY HOUSE:

1) Remove all poultry and feeds from premises, trucks, coops, and crates.
2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3) Empty all troughs, racks, and other feeding and watering appliances.
4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes.
6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.
***NOTE:** The fog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.
FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

PRECAUTIONARY STATEMENTS
Hazards to humans and domestic animals

DANGER
KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

FIRST AID
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.
IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.
HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Net Contents: _____ U.S. Gallons Batch No.:_____

Manufactured By:
PRESERVE INTERNATIONAL
Zephyr Cove, NV 89448 (209) 664-1607 • www.preserveinternational.com

DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm $CaCO_3$) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

DIRECTIONS FOR USE:

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5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

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SYNERGIZE

CLEANER-DISINFECTANT

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Staphylococcus aureus A.T.C.C. 6538 — Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella choleraesuis A.T.C.C. 10708 — Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS) — Avian Influenza
Escherichia Coli F18

ACTIVE INGREDIENTS

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Glutaraldehyde	7.00%
INERT INGREDIENTS	67.00%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

REVISED
AFTER COMMENTS
in EPA Letter Dated:
AUG 22 2006

EPA Registration No.: 66171-7
EPA Establishment No.: 66171-TA-001
66171-CA-001

Patent Number: 5,891,922

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 66171-7

NFPA HAZARD CLASSIFICATION

HEALTH	FIRE	REACTIVITY	SPECIFIC
3	1	1	None

Manufactured By:

PRESERVE INTERNATIONAL

Zephyr Cove, NV 89448 (209) 664-1607 • www.preserveinternational.com

PRECAUTIONARY STATEMENTS
Hazards to humans and domestic animals

DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Net Contents: _____ U.S. Gallons Batch No.:_____

Decision #: 365344

DATA PACKAGE BEAN SHEET

DP #: (327570)

Date: 31-May-2006

* * * Registration Information * * *

Registration: 66171-7 - SYNERGIZE

Company: 66171 - PRESERVE INTERNATIONAL

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8219

Risk Manager Reviewer: Jacqueline Campbell-McFarlane JMCFAR02

Sent Date: _____ Calculated Due Date: 23-Aug-2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A57) AMENDMENT;NON-FAST TRACK;

Ingredients: 043901, Glutaraldehyde(7%)

069175, Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18)(26%)

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 10-Mar-2006 Due Back: _____

DP Ingredient: 043901, Glutaraldehyde

069175, Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18)

DP Title: Efficacy Evaluation

CSF Included: ○ Yes ● No Label Included: ● Yes ○ No Parent DP #: _____

Assigned To		Date In	Date Out	
Organization:	AD / PSB	13-Mar-2006		Last Possible Science Due Date: 24-Jul-2006
Team Name:	EET	13-Mar-2006	6/2/06	Science Due Date: 18-Jun-2006
Reviewer Name:	Laniyan, Ibrahim	25-Apr-2006	31-May-2006	Sub Data Package Due Date: 04-Jun-2006
Contractor Name:	DynCorp	14-Mar-2006	24-Apr-2006	

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Registrant wants to add 2 organisms to the label: Avian Influenza (H3N2) Virus (467703-01) and E. coli F18 (MRID 467703-02)

PRIA tentative start date: March 20, 2006

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 31, 2006

MEMORANDUM

Subject: Efficacy Review for Synergize, EPA Reg. No. 66171-7; DP Barcode: D327570

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510C)

Thru: Nancy Whyte, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Velma Noble / Jacqueline Campbell-McFarlane
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: Preserve International
Zephyr Cove, NV 89448

Formulation from the Label:

Active Ingredient(s)	% by wt.
Alkyl (67% C_{12}, 25% C_{14}, 7% C_{16}, 1% C_{18}) dimethyl benzyl Ammonium Chlorides	26.00 %
Glutaraldehyde	7.00 %
Inert Ingredients	67.00 %
Total	100.00 %

I. BACKGROUND

The product, Synergize (EPA Reg. No. 66171-7), is an EPA-approved disinfectant (bactericide, fungicide, virucide) for use on hard, non-porous surfaces in farming and animal and poultry care environments. The label claims that the product is effective in the presence of 1000 ppm hard water and 5% serum. The applicant requested an amendment to the registration of this product to add claims for effectiveness against Avian Influenza A virus (H3N2) and *Escherichia coli* (F-18). Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated February 16, 2006), two studies (MRID Nos. 467703-01 and 467703-02), Statements of No Data Confidentiality Claims for the study assigned MRID No. 467703-01, and the proposed label.

II. USE DIRECTIONS

The product is designed for use in disinfecting hard, non-porous surfaces such as appliance exteriors, floors, garbage cans, sinks, tables, telephone booths, and walls. The label indicates that the product may be used on hard, non-porous surfaces including: fiberglass, glass, glazed ceramic, glazed tiles, metal (e.g., aluminum, brass, chrome, galvanized metal, stainless steel, tin), plastic (e.g., acrylic, polyethylene, polypropylene, polyvinyl chloride, vinyl), and treated wood. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Remove all animals/poultry and feed. Empty feeding and watering appliances. Remove all gross soil, bedding, manure, caked on dirt, etc. Pre-clean surfaces with soap or detergent and rinse with water. Prepare a use solution by adding 0.5 ounces of the product to 1 gallon of water (a 1:256 dilution). Apply the use solution with a cloth, sponge, mop, or mechanical coarse spray device until surfaces are thoroughly wet. Treated surfaces must remain wet for 10 minutes. Rinse with clean water. Allow to air dry. Food contact surfaces must be scrubbed with soap or detergent and rinsed with potable water prior to use.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-

Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 467703-01 "Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (H3N2) virus (Avian Reassortant)" for Synergize, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – January 25, 2006. Project Number A03539.

This study was conducted against Avian Influenza A (H3N2) virus (Avian Reassortant) (ATCC VR-2072; Strain A/Washington/897/80 X A/Mallard/New York/6750/78), using Rhesus monkey kidney cells (RMK cells; originally obtained from ViroMed Laboratories, Inc.; maintained in-house) as the host system. Two lots (Lot Nos. 32585 and 32645) of the product, Synergize, were tested according to ATS Labs Protocol No. PRE08110705.AFLU.2 (copy not provided). A use solution was prepared by adding 1ml of the product to 255 ml of 1000ppm AOAC synthetic hard water (titrated at 1003ppm; a 1:256 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.1°C at 54% relative humidity for 20 minutes. For each lot of product, separate dried virus films were treated with 2.0ml of the use solution for 10 minutes at 20.1°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was neutralized by adding 18.0 ml of serum-free Minimum Essential Medium supplemented with 10µg/ml gentamicin, 100units/ml penicillin, and 2.5µg/ml amphotericin B. Serial 10-fold dilutions were prepared using Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5µg/ml amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls

included those for dried virus counts, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.0 $\log_{10}$** for both batches.

2. MRID 467703-02 "AOAC Use-Dilution Method, Test Organism: *Escherichia coli* (F-18) - Clinical Isolate" for Synergize, by Amy Jeske. Study conducted at ATS Labs. Study completion date – January 23, 2006. Project Number A03572.

This study was conducted against *Escherichia coli* (F-18) - Clinical Isolate (obtained from the U.S. Department of Agriculture, College Station, TX). Two lots (Lot Nos. 32585 and 32645) of the product, Synergize, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A use solution was prepared by adding 1.0ml of the product to 255.0 ml of 1000ppm AOAC synthetic hard water (titrated at 1003ppm; a 1:256 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0ml broth. The carriers were dried for 40 minutes at 35-37°C at 40% relative humidity. Each carrier was exposed to 10 ml of the use solution for 10 minutes at 20±1°C. Following exposure, the carriers were transferred to 10 ml of Letheen Broth with 0.1% sodium bisulfite to neutralize. The carriers were transferred to secondary subculture tubes containing 10ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes after the first subculture. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Escherichia coli*** **4.0×10^4**.

Notes: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

The laboratory report is missing page 2, which is likely the "Statement of No Data Confidentiality Claims."

V. RESULTS

MRID #	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population Count (CFU/carrier)
		Lot No. 32585	Lot No. 32645	
467703-02	**Escherichia coli *(F-18)-Clinical Isolate***	1°=0/10 2°=0/10	1°=0/10 2°=0/10	4.0×10^4

MRID #	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 ml)
			Lot No. 32585	Lot No. 32645	
467703-01	Avian Influenza A (H3N2) virus (Avian Reassortant)	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$
		$TCID_{50}$/0.1 ml	$\leq 10^{1.5}$	$\leq 10^{1.5}$	

VI. CONCLUSIONS

1. The submitted efficacy data (MRID No. 467703-02) support the use of the product, Synergize, as a disinfectant against *Escherichia coli* (F-18) on hard, non-porous surfaces in the presence of 1000ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:256 dilution. Killing was observed in the subcultures of all carriers tested against the required number of product lots. Carrier population counts were at least 10^4. Neutralization confirmation testing showed positive growth of the microorganism. The viability controls were positive for growth. Purity controls were reported as pure. The sterility controls did not show growth.

2. The submitted efficacy data (MRID No. 467703-01) support the use of the product, Synergize, as a disinfectant with virucidal activity against Avian Influenza A (H3N2) virus (Avian Reassortant) on hard, non-porous surfaces in the presence of 1000ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:256 dilution. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was observed in all dilutions tested.

VII. RECOMMENDATIONS

Please note: The species name of the organism *Salmonella* ***choleraesuis*** has been changed by ATCC. The new designation of this organism is *Salmonella* ***enterica***. This change is effective immediately, and should be used for all subsequent references to this organism in the future.

1. The proposed label claims that the product, Synergize, is an effective disinfectant against *Escherichia coli* F18 and Avian Influenza on hard, non-porous surfaces in the presence of 1000 ppm $CaCO_3$ and 5% serum for a contact time of 10 minutes at a 1:256 dilution, **are supported** by the applicant's data.

2. The proposed label indicates that the product may be used on fiberglass surfaces. Fiberglass is a porous surface. **The applicant must delete this general reference to fiberglass**. The applicant may indicate on the product label that the product may be used on sealed fiberglass surfaces.

3. Please make the following change, as appropriate:

- Under the "Use Directions" section regarding vehicles, change "**course** spray" to read "**coarse** spray."

MEMORANDUM

DATE: April 19, 2006

SUBJECT: Efficacy Review for Synergize, EPA Reg. No. 66171-7; DP Barcode: D327570

FROM: CSC Systems & Solutions LLC (CSS)

THRU: Wallace Powell
Antimicrobials Division

TO: Nancy Whyte
Antimicrobials Division

APPLICANT: Preserve International
Zephyr Cove, NV

I BACKGROUND

The product, Synergize (EPA Reg. No. 66171-7), is an EPA-approved disinfectant (bactericide, fungicide, virucide) for use on hard, non-porous surfaces in farming and animal and poultry care environments. The label claims that the product is effective in the presence of 1000 ppm hard water and 5% serum. The applicant requested an amendment to the registration of this product to add claims for effectiveness against Avian Influenza A virus (H3N2) and *Escherichia coli* (F-18). Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated February 16, 2006), two studies (MRID Nos. 467703-01 and 467703-02), Statements of No Data Confidentiality Claims for the study assigned MRID No. 467703-01, and the proposed label.

Note: CSS downloaded the last accepted label (March 4, 2005) from the Internet.

II USE DIRECTIONS

The product is designed for use in disinfecting hard, non-porous surfaces such as appliance exteriors, floors, garbage cans, sinks, tables, telephone booths, and walls. The label indicates that the product may be used on hard, non-porous surfaces including: fiberglass, glass, glazed ceramic, glazed tiles, metal (e.g., aluminum, brass, chrome, galvanized metal, stainless steel, tin), plastic (e.g., acrylic, polyethylene, polypropylene, polyvinyl chloride, vinyl), and treated wood. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Remove all animals/poultry and feed.

Empty feeding and watering appliances. Remove all gross soil, bedding, manure, caked on dirt, etc. Pre-clean surfaces with soap or detergent and rinse with water. Prepare a use solution by adding 0.5 ounces of the product to 1 gallon of water (a 1:256 dilution). Apply the use solution with a cloth, sponge, mop, or mechanical coarse spray device until surfaces are thoroughly wet. Treated surfaces must remain wet for 10 minutes. Rinse with clean water. Allow to air dry. Food contact surfaces must be scrubbed with soap or detergent and rinsed with potable water prior to use.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as

5 percent serum. These Agency standards are presented in DIS/TSS-2. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 467703-01 "Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (H3N2) virus (Avian Reassortant)" for Synergize, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – January 25, 2006. Project Number A03539.

This study was conducted against Avian Influenza A (H3N2) virus (Avian Reassortant) (ATCC VR-2072; Strain A/Washington/897/80 X A/Mallard/New York/6750/78), using Rhesus monkey kidney cells (RMK cells; originally obtained from ViroMed Laboratories, Inc.; maintained in-house) as the host system. Two lots (Lot Nos. 32585 and 32645) of the product, Synergize, were tested according to ATS Labs Protocol No. PRE08110705.AFLU.2 (copy not provided). A use solution was prepared by adding 1 mL of the product to 255 mL of 1000 ppm AOAC synthetic hard water (titrated at 1003 ppm; a 1:256 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.1°C at 54% relative humidity for 20 minutes. For each lot of product, separate dried virus films were treated with 2.0 mL of the use solution for 10 minutes at 20.1°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was neutralized by adding 18.0 mL of serum-free Minimum Essential Medium supplemented with 10 μg/mL gentamicin, 100 units/mL penicillin, and 2.5 μg/mL amphotericin B. Serial 10-fold dilutions were prepared using Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 μg/mL gentamicin, 100 units/mL penicillin, and 2.5 μg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus counts, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

2. MRID 467703-02 "AOAC Use-Dilution Method, Test Organism: *Escherichia coli* (F-18) - Clinical Isolate" for Synergize, by Amy Jeske. Study conducted at ATS Labs. Study completion date – January 23, 2006. Project Number A03572.

This study was conducted against *Escherichia coli* (F-18) - Clinical Isolate (obtained from the U.S. Department of Agriculture, College Station, TX). Two lots (Lot Nos. 32585 and 32645) of the product, Synergize, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. A use solution was prepared by adding 1.0 mL of the product to 255.0 mL of 1000 ppm AOAC synthetic hard water

(titrated at 1003 ppm; a 1:256 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 40% relative humidity. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20±1°C. Following exposure, the carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium bisulfite to neutralize. The carriers were transferred to secondary subculture tubes containing 10 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes after the first subculture. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The laboratory report is missing page 2, which is likely the "Statement of No Data Confidentiality Claims."

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population Count (CFU/ carrier)
		Lot No. 32585	Lot No. 32645	
467703-02	*Escherichia coli* (F-18) - Clinical Isolate	1°=0/10 2°=0/10	1°=0/10 2°=0/10	4.0×10^4

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 mL)
			Lot No. 32585	Lot No. 32645	
467703-01	Avian Influenza A (H3N2) virus (Avian Reassortant)	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$
		$TCID_{50}$/0.1 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 467703-02) support the use of the product, Synergize, as a disinfectant against *Escherichia coli* (F-18) on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:256 dilution. Killing was observed in the subcultures of all carriers tested against the required number of product lots. Carrier population counts were at least 10^4. Neutralization confirmation

testing showed positive growth of the microorganism. The viability controls were positive for growth. Purity controls were reported as pure. The sterility controls did not show growth.

2. The submitted efficacy data (MRID No. 467703-01) support the use of the product, Synergize, as a disinfectant with virucidal activity against Avian Influenza A (H3N2) virus (Avian Reassortant) on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:256 dilution. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was observed in all dilutions tested.

VII RECOMMENDATIONS

1. The proposed label claims that the product, Synergize, is an effective disinfectant against *Escherichia coli* F18 and Avian Influenza on hard, non-porous surfaces in the presence of 1000 ppm $CaCO_3$ and 5% serum for a contact time of 10 minutes at a 1:256 dilution. Data provided by the applicant support these claims.

2. The proposed label indicates that the product may be used on fiberglass surfaces. Fiberglass is a porous surface. The applicant must delete this general reference to fiberglass. The applicant may indicate on the product label that the product may be used on sealed fiberglass surfaces.

3. Please make the following change, as appropriate:

- Under the "Use Directions" section regarding vehicles, change "course spray" to read "coarse spray."

returned from contractor 4/20/06

E429

TASK ASSIGNMENT FORM(TAF)

Antimicrobial Division/OPP--*Effective June 5, 1998*

PO:

A -- Completed by Reviewer/Team Leader (*check(√) or complete appropriate boxes*)					
RASSB____	**PSB**____	**Product Toxicology**	**Human Toxicology**_	**Product Chemistry**	**Efficacy** X
Chemical: Glutaraldehyde				**DP Barcode:** 327570	
Type: Registration RED _ Prod. Reregistration FQPA PRIA X Special Project _ Lit. Search_ Other:					
Due Date: 4/25/06	**AD Contact:** Nancy Whyte			**Team Leader:** Nancy Whyte	

B - Completed by Reviewer/Team Leader				**C - Completed By Contractor**
Study/Action	**MRID**	**GDLN #**	**Gov't Est Hrs**	**Tech Hrs. Spent**
Virucidal Efficacy of Disinfectants for Use On Inanimate Environmental Surfaces - Virus: Avian Influenza A (H3N2) virus (Avian reassortant)	467703-01	91-2	5	
AOAC Use- Dilution Method Test Organism: Escherichia coli (F-18) - Clinical Isolate	467703-02	91-2	5	
		Total	10	6

Review Instructions/Comments:

D -- Completed by WAM/PO

PRESERVE
INTERNATIONAL
www.PreserveInternational.com

467703-00

Office of Gary E. Gaumer P.O Box 17003, Reno, NV 89511 • Bus (775) 853-9776 • Fax: (775) 853-9212 • email: gegaumer@preserveinc.com

February 16, 2006

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

1 Amendment to add Avian Influenza Virus to the label.
2 Amendment to add Escherichia Coli F18

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,
Preserve International

Gary E. Gaumer
President

46770301 VIRUCIDAL EFFICACY OF DISINFECTANTS FOR USE ON INANIMATE ENVIRONMENTAL SURFACES

46770302 AOAC USE-DILUTION METHOD